

Psychometric Properties of Knowledge, Attitude, and Practice on Pharmacogenovigilance in Drug Safety Questionnaire in Medicine and Pharmacy Students: based on Exploratory Factor Analysis

Adamu Yau¹, Rohayah Husain¹, Aniza Abd Aziz¹, Mohd Khairi Bin Zahri Johari², Ab Fatah Bin Rahman², Ramadan Mohamed Elkalimi³, Ya'u Jamilu⁴, Mainul Haque^{1*}

¹Faculty of Medicine, Universiti Sultan Zainal Abidin, Kampus Kota, Jalan Sultan Mahmud, 20400 Kuala Terengganu, Malaysia. ²Faculty of Health Sciences, Universiti Sultan Zainal Abidin, Kampus Kota, Jalan Sultan Mahmud, 20400 Kuala Terengganu, Malaysia. ³Kulliyyah of Pharmacy, International Islamic University Malaysia, Kuantan, Malaysia. ⁴Department of Pharmacology and Therapeutics & Department of Clinical Pharmacy and Pharmacy Practice, Faculty of Pharmaceutical Sciences, Ahmadu Bello University, Zaria, +234 Zaria, Nigeria.

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ABSTRACT

Integration of Pharmacogenomics and Pharmacovigilance in the curricula of future healthcare professionals is essential towards individualized medicine and drug safety. Researchers are lacking in Knowledge, attitude and practice regarding pharmacogenovigilance in drug safety among Malaysian future health professionals. This study is to develop and validate a reliable questionnaire for evaluation of knowledge, attitude and practice of future Doctors and Pharmacists concerning Pharmacogenovigilance in drug safety. A 49-item self-administered questionnaire was developed from the literature. The content was validated by a panel of relevant experts followed by face validity. A pilot study on 100 respondents was conducted for reliability, followed by a cross-sectional study involving 247 participants in factor analysis. The content validity index of the whole questionnaire was 0.8%. The overall Cronbach's Alpha was 0.8, with $P < 0.001$. 67.4% of the total variance was explained by 13 factors, and we can conclude that the questionnaire is a valid and reliable instrument.

INTRODUCTION

Pharmacogenomics is the study of variability in pharmacokinetics and pharmacodynamics in relation to genetic variations. If genetic factors are taken into account appropriately prior to drug treatment, the regimen can be personalized to the individual patient need, hence promote drug safety. Clinicians are increasingly anticipated to incorporate pharmacogenomics into practices, but this expectation has been below projected. Therefore, it is important that future physicians and pharmacists are exposed to these important areas. A measuring tool like questionnaire could assist medical educators and health care providers in evaluating the teaching programs for future Doctors and Pharmacists and necessity of retraining. Previous studies revealed an urgent requirement for greater emphasis on practice

and knowledge of pharmacogenomics and pharmacovigilance among healthcare professionals (Adamu *et al.*, 2015a; Adamu *et al.*, 2015b). Presently, a standardized questionnaire of knowledge, attitude, and practice of Medicine and Pharmacy students concerning pharmacogenovigilance for drug safety is unavailable. Questionnaires that reported either pharmacovigilance or pharmacogenomics of Medicine and Pharmacy students are also infrequently seen and used on students (Elkalimi *et al.*, 2011; Filiptsova *et al.*, 2014). This research would focus on medicine and pharmacy students to identify their strength and weaknesses for the possibility of providing educational and concrete recommendations. This aimed at developing and reporting the psychometric properties of knowledge, attitude, and practice (KAP) on Pharmacogenovigilance in Drug Safety Questionnaire in final-year Medicine and Pharmacy Students: based on Exploratory Factor Analysis. The questionnaire could be used in the assessment of awareness, attitude and practice concerning pharmacogenovigilance. It can also be used by policy makers, community programmers and medical educators for evaluation and or recommendations.

* Corresponding Author

Prof (Dr.) Mainul Haque, Faculty of Medicine, Universiti Sultan Zainal Abidin, Kampus Kota, Jalan Sultan Mahmud, 20400 Kuala Terengganu, Malaysia. Email: runurono@gmail.com

Item Standardization

Healthcare professionals must be equipped with the required skills in evaluating the quality of reported outcomes in the literature and obtained from measurement tools in clinical practice. These results are frequently assessed using instruments such as scales, education tests, questionnaires, and observer ratings that attempt to measure factors such as signs, symptoms, knowledge, attitudes, or skills in various settings of medical systems (Cook and Beckman, 2006). The validity of an instrument refers to “the extent to which evidence and principle support the interpretations of test scores entailed by the intended application of tests (Aday and Cornelius, 2006). It describes how deeply one can justifiably trust the outcomes of a test for a particular purpose as interpreted. Many measuring tools measure a physical quantity such as weight, height, blood pressure, or BMI. Finding from such tools can be interpreted directly. In contrast, findings from assessments of patient signs and symptoms, physician knowledge, or student attitudes have no intrinsic meaning. Rather, they try to measure a particular construct, which is not concrete and physical quantity, but a collection of abstract models and central beliefs. The findings from any psychometric evaluation have significance (validity) only in the circumstance of the intended construct (Kimberlin and Winterstein, 2008). Some sources of evidences used to support construct validity include: content, internal structure, response process, relations to other variables, and consequences (Auewarakul *et al.*, 2005; Beckman *et al.*, 2005). These are the only sources of evidence that can be generated to support the construct validity of interpretations made from the results of measurement by the instrument, but rather they are not a subdivision of validity. Multiple sources should be considered in generating evidences to support any given inferences, and irrespective of the quality and strength of a single source-evidence, evidence from other sources must be explored (Cizek *et al.*, 2007; Downing, 2003). While generating evidence to support validity, emphasis should be placed precisely on two threats to validity: construct underrepresentation (inadequate sampling of the content domain) and factors if non-random influence on scores (bias) (Cook and Beckman, 2006; Downing and Haladyna, 2004).

MATERIALS and METHODS

Study Population

The study covers four randomly selected Malaysia universities, including two public and two private schools. The population included a sample of final-year pharmacy and medical students who were enrolled full-time at public or private schools during the study period with informed consent. In this cross-sectional observational study, final-year Medicine and Pharmacy students because of that they must have taken almost all the prerequisite courses for graduation. Registered final-year Medical and or Pharmacy students at a Malaysian University at the time of the study and interested in participating in the study (with informed consent) were included, while for exclusion criteria involved final year Medicine or Pharmacy students that

participated in the pilot study, and or mentally or psychologically unstable persons and or those decided not to participate by disagreeing in the consent form. The sample size for this factor analysis was calculated using the rule of thumb: minimum of 5 sample per one item (Costello and Osborne, 2005). Our questionnaire contains 49 items, hence $49 \times 5 = 247$. Therefore, this study was conducted on 247 participants to find out that if our most significant domains (knowledge, attitude, and practice) were characterized by this analysis in the same intention which were categorized initially.

Designing and Standardizing the Questionnaire

A 59-item self-administered questionnaire were structured for assessing basic knowledge of pharmacogenovigilance; familiarity and awareness about pharmacogenovigilance; roles of pharmacogenovigilance in drug safety; training on Pharmacogenomics and Pharmacovigilance towards drug safety; understanding of basic Pharmacogenomics, and Pharmacovigilance in drug safety; adverse drug reaction (ADRs); perceive pharmacogenomic knowledge and individualized medicine. For attitudes; questions were designed on attitude towards perceiving benefits; risks involved in Pharmacogenomics; interest on pharmacogenovigilance and drug safety; the importance of pharmacogenovigilance; ethical concerns towards Pharmacogenomics and Pharmacovigilance in drug safety. For practice questions, activities such as lectures on genetic variation in relation to medicine; asking questions about Pharmacogenomics, Pharmacovigilance and adverse drug reactions; reading and discussion about Pharmacogenomics, Pharmacovigilance and ADRs; application of pharmacogenovigilance towards drug safety were designed. The questionnaire used the Likert scale; yes/no and always, monthly, every semester, once in my program or never for practice section. Lastly, some demographics (age, gender, ethnicity, specialty, University type and nationality) were included.

Item Generation

The initial draft of 59-item self-administered questionnaire was developed through search into the available literature and frequently ask questions (FAQs) (Adam *et al.*, 2015a; Benzeroual *et al.*, 2012; Filiptsova *et al.*, 2015; Formea *et al.*, 2013; Stanek *et al.*, 2013; Taber and Press, 2014). An expert panel was formed in order to design flowchart and for characterizing the primary domains of our KAP survey. Then, we detailed our primary areas to some questions. Experts in the field of Public Health (Biostatistician; specifically specialize in designing the questionnaire), Associate Professor and consultant psychiatrist, Professor of Pharmacology, a Professor of clinical Pharmacology, a pharmacogenomic expert, an Associate Professor of Pharmacy practice and an Associate Professor of pharmacology and ethnopharmacology were the composition of our expert panel.

Item Modification

Comments and observations from experts working in the area of Epidemiology, Biostatistics, Pharmacovigilance and

Pharmacogenomics studies were sought during 3rd questionnaire development and validation workshop held 25-28th August, 2014 at the unit of Biostatistics and research methodology, Universiti Sains Malaysia. According to the experts' objective opinions, the wording, content and the structure of some questions had been modified.

Item Reduction (Factor Analysis)

Factor analysis provides an enhanced understanding of which variables form a "relatively coherent subset, independent of others" (Cook and Beckham 2006; Fafrigar *et al.*, 1999). This study was conducted on 247 participants to find out that if our most significant domains KAP were characterized by this analysis in the same intention which were categorized initially. The study design was cross-sectional, which was intended to reduce the items into their appropriate domains. The questionnaire was distributed face to face to the study participants by the principal author.

Reliability

Measurement reliability means reproducibility, repeatability, consistency or precision of the instrument (Fletcher *et al.*, 1996; Gordis, 2009; Trochim and Donnelly, 2006). A pilot study on 100 respondents was conducted for the purpose of reliability determination. The sample size was calculated by statstodo-software <http://www.statstodo.com/SSiz1AlphaPgm.php>. The questionnaire was distributed face to face to the study participant with an informed written consent. At the end of 2 weeks period, 60 % of the participants responded. There were 2 incomplete questionnaire and were subsequently removed out of the valid responses. A reliability coefficient value of 0 represents no correlation (all error), whereas the value of 1 represents the absolute relationship between items (all variances attributable to subjects). Acceptable limit usually varies according to the intended use of the measuring tool. For high-stakes settings (e.g., licensure examination) the acceptable reliability value should be greater than 0.9 whereas for less critical conditions values of 0.8 or 0.7 are usually acceptable (Cook and Beckman, 2006).

Face Validity

It is usually used to describe the form of validity in the absence of first-hand testing. The concepts of content evidence and face validity are apparently similar but are in fact quite different. Whereas content validity entails a systematic professional and documented approach to ensure that the instrument measures the intended construct accurately, face validity involves judgment on the appearance and understanding of each item of the instrument. Of significance concerns also are imperfection of assessments based on appearance, heterogeneous perceptions between developers and users, and in some cases counterproductive judgments from appearance might occur (Kimberlin and Winterstein, 2008; Montazeri *et al.*, 2005). This study a separate sample of 20 participants that fulfilled the inclusion criteria were asked to objectively and constructively assess the degree of clarity

(whether there were ambiguities or multiple ways to interpret the question) and comprehension (whether words and sentences of the constructed items can be understood easily by respondents) of each element to measure domains. The rating was done using a 5-point Likert scale from 1 = the sentence is very vague, 2 = the sentence is vague, 3 = the sentence is acceptably clear, 4 = the sentence is clear, 5 = the sentence is very clear for degree of clarity and 1 = the sentence is tough to be understood, 2 = the sentence is hard to be understood, 3 = the sentence is acceptable to be understood, 4 = the sentence is easy to be understood, 5 = sentence is very easy to be understood for the degree of comprehension. The face validity index (FVI) for Knowledge, attitude and practice were calculated followed by calculation of the content validity index of the whole KAP questionnaire.

Content Validity

The validity of an instrument measuring non-concrete concept (construct), in which there is no criterion or directly observable phenomenon of the notion Cronbach and Meehl 1955. It evaluates the "relationship between a test's content and the domain it is intended to measure (Aday and Cornelius, 2006). The content should symbolize the truth (domain), the whole truth (domain), and nothing but the truth (domain). Therefore, we consider the concept definition, the intended purpose of the instrument, the process for identifying, developing and selecting items, the wording of individual items in our questionnaire, and the background, qualifications and experience of item writers, evaluators and reviewers. The content validity of the final questionnaire was determined by the settings panel of 7 experts in the field of Public Health (Biostatistician; specifically specialize in designing the questionnaire), Associate Professor and consultant psychiatrist, Professor of Pharmacology, a Professor of clinical Pharmacology, a pharmacogenomic expert, an Associate Professor of Pharmacy practice and an Associate Professor of pharmacology and ethnopharmacology. Each expert was asked to objectively and constructively judge the degree of relevancy (the extent to which each item relates to the aspect of the domain/subscale) using rating scale 1 = the issue is very irrelevant to the measured domain, 2 = item is irrelevant to the measured domain, 3 = the item is acceptable relevant to the measured domain, 4 = the item is relevant to the measured domain, 5 = the item is very relevant to the measure domain and degree of representativeness (how completely the item covers the associated aspect of the domain) using rating scale 1 = the item is totally not representing the domain, 2 = the item is minimally representing the domain 3 = the item is satisfactory representing the domain, 4 = adequately representing the domain, 5 = the item is accurately representing the domain for each question of the questionnaire. They examined each statement for omissions and or inappropriate choice of items. A qualitative response, guidance was provided for some items so that the evaluators would know how some specific questions should be answered. The content validity index for Knowledge,

attitude and practice were calculated following by calculation of the content validity index of the whole KAP questionnaire.

Data Analysis

The data were explored for wrong entry, missing value. Internal consistency of the questionnaire using reliability statistics of Cronbach's Alpha coefficient was calculated using IBM*SPSS 20.0 for windows. Factor analysis (Exploratory factor analysis) was employed for data reduction and tailoring the related items into theoretically similar and statistically related domains. Principal Component Analysis was used for extraction and Varimax with Kaiser Normalization (orth.) rotation to get maximum variance explained (Hair *et al.*, 2009). A number of factors were extracted based on several factors, i.e., Eigenvalue larger than 1, Scree plot & factor loading (Fabrigar *et al.*, 1999; Ledesma *et al.*, 2007). Kaiser-Meyer-Olkin (KMO) measure of sampling adequacy and Bartlett's test of the sphericity value of greater than 0.7 and less than 0.005 were used, respectively, and factor loading of 0.3 was considered as cut off point. Demographic variables were presented as frequency and percentage using descriptive statistics. The differences and correlations were being considered statistically significant at $P < 0.05$. The Content Validity Index (CVI) and face validity index (FVI) were calculated using giving formulae.

Ethical Approval: The study has been reviewed by the Universiti Sultan Zainal Abidin (UniSZA) and UHREC (UniSZA Human Research Ethics Committee) and granted approval with reference number: UniSZA.N /1/628- (69) dated 21st July, 2014 (23rd Ramadhan 1435H) before commencement of the research. Permission to approach the students was officially obtained from the Deans of their respective faculties. All Participants were briefed on the research, and they have all signed an informed written consent before participating in the study.

RESULTS

The developed questionnaire was 6 pages in length and consisted of 60 items classified into the following areas. The first part consisted of 11 items, which covering demographic characteristics of the respondents such as gender, age, discipline, ethnicity, type of university and Nationality. The second part consisted of 49 items exploring the knowledge, attitudes and practice regarding Pharmacogenomics and pharmacovigilance in drug safety. After the analysis, final extracted items consisted of 42 questions. The first 17 items were constructed as a series of yes/no statements, and the participants were asked to indicate their response accordingly. The next 15 items were constructed in forms of statement asking the respondents to indicate their agreement or disagreement using a 5-point Likert scale format (5 = "strongly agree," 4 = "agree," 3 = "neutral," 2 = "disagree," and 1 = "strongly disagree"). The rest of the questions (10 items) also used a 5-point Likert scale. The classification of these items in a particular domain was not disclosed to the participant before distributing the questionnaire to them.

Demographic Characteristics of Study Participants

Within four-month study period, a response rate of 68.4% was recorded, and there was no incomplete response from the respondents. Age, date of birth, gender, marital status, religion, ethnicity, nationality, discipline and University type of the respondents were collected demographic variables. The majority of the participants were medical students, and female students accounting for 63.3% and 69.85 respectively, with a significant difference between the professions. The mean age of the respondents was 22.98 ± 1.03 years old, with pharmacy students (22.03 ± 0.44) younger than the medical students (23.53 ± 0.85). The majority (52.7%) of the respondents were Malay, followed by Chinese (37.9%), then Indians (7.7%), Bumiputra (1.2%) and others (0.6%).

Psychometric Properties

Face Validity

The calculated face validity index (FVI) results from 10 final year Medicine students, and 10 final year Pharmacy students were presented in Table 1. And it shows that the face validity index-clarity (FVI-Clarity) is 0.80, face validity index-comprehension (FVI-comprehension) is 0.87 and total face validity index (FVI) is 0.835. Therefore, all values fall above 0.5 cutoff point.

Table 1: Face and Content Validity Index of KAP questionnaire.

| S/N | Variables | Value |
|-----|------------------------------|-------|
| 1 | Content Validity Index (CVI) | 0.819 |
| | C VI-relevancy | 0.820 |
| | CVI-Representativeness | 0.818 |
| | Total | 0.819 |
| 2 | Content Validity Index (FVI) | 0.835 |
| | FVI-Comprehension | 0.870 |
| | FVI-Clarity | 0.800 |
| | Total | 0.835 |

Content Validity

From our findings, the content validity index-relevancy (CVI-relevancy) is 0.820, content validity index-representativeness (CVI – representativeness) is 0.818 and total Content validity index (CVI) is 0.819 as shown in Table 1., therefore, the results of Content validity index (CVI) from seven experts were greater than 0.5 and were considered as acceptable and meritorious

Internal consistency (Reliability)

For reliability, uniformity and precision, Cronbach's Alpha scores > 0.7 , Corrected Item-total correlation > 0.5 and the values of Cronbach's Alpha if item deleted were considered and checked for each construct as extracted from EFA. Selected useful items by construct were involved in the analysis as shown in Table 2, 3 and Table 4.

Table 2: Results of Exploratory Factor Analysis (EFA)-Factor 1.

| Factor | Item | Factor Loading | Corrected item Total correlation | Cronbach's alpha If item deleted | Cronbach's alpha |
|-----------|--|----------------|----------------------------------|----------------------------------|------------------|
| Knowledge | Q1. All medicines in the market are safe. | 0.455 | 0.324 | 0.777 | 0.784 |
| | Q2. All traditional medicines are safe because they are natural products | 0.463 | 0.279 | 0.780 | |
| | Q4. ADR is any response to medicines that is unintended and occurs at normal doses used in humans | 0.371 | 0.317 | 0.778 | |
| | Q5. Cytochrome P450 (CYP450) is a drug metabolizing enzyme which has been affected by genetic variations | 0.410 | 0.393 | 0.772 | |
| | Q6. Pharmacovigilance is about drug safety | 0.451 | 0.382 | 0.773 | |
| | Q7. Public awareness on drug safety information is part of Pharmacovigilance | 0.503 | 0.493 | 0.763 | |
| | Q8. Genetic variation is a risk factor to adverse drug reaction. | 0.597 | 0.470 | 0.766 | |
| | Q9. Pharmacogenetics is the study of drugs responses in relation to human genetics variations. | 0.776 | 0.579 | 0.761 | |
| | Q10. Pharmacogenetics aims at understanding the roles of human genetic variations in drugs safety. | 0.704 | 0.505 | 0.762 | |
| | Q11. Drug responses to genetic variations influence Pharmacovigilance. | 0.639 | 0.400 | 0.772 | |
| | Q12. Genetic variations in drug metabolizing enzymes affect drug therapy | 0.568 | 0.424 | 0.769 | |
| | Q14. The anticoagulant effects of warfarin have been known to be affected by genetic variations. | 0.387 | 0.523 | 0.764 | |
| | Q15. Genetic variations affect Pharmacological action of some NSAIDs | 0.282 | 0.331 | 0.777 | |
| | Q17. Genetic variations influence the pharmacological effects of Carbamazepine | 0.291 | 0.326 | 0.778 | |
| | Q18. Genetics information is now a requirement for some drug labels, according to Food and Drug Administration (FDA). | 0.395 | 0.291 | 0.781 | |
| | Q19. Based on the drug metabolizing enzymes activity, people can be classified into: a. poor metabolizers, b. slow metabolizers C. ultra-rapid metabolizers, d. all of the above | 0.302 | 0.175 | 0.791 | |

Table 3: Results of Exploratory Factor Analysis (EFA)-Factor 2

| Factor | Item | Factor Loading | Corrected item Total Correlation | Cronbach's Alpha If item Deleted | Cronbach's Alpha |
|----------|--|----------------|----------------------------------|----------------------------------|------------------|
| Attitude | Q16. Reading information about Adverse drug reactions is very difficult | 0.306 | 0.399 | 0.830 | 0.836 |
| | Q20. Genetic tests are now available in Malaysia | 0.338 | 0.509 | 0.823 | |
| | Q21. Genetic tests could be ready in the laboratory within 48hours | 0.350 | 0.556 | 0.820 | |
| | Q25. I believe that ADRs is a problem that deserves attention | 0.425 | 0.646 | 0.815 | |
| | Q26. I believe that pharmacovigilance is my professional obligation | 0.532 | 0.480 | 0.825 | |
| | Q28. I would agree to do genetic test in order to determine the initial dose of related drug if I were patient | 0.640 | 0.628 | 0.814 | |
| | Q29. I believe that pharmacovigilance plays essential roles in preventing drug related problems | 0.703 | 0.402 | 0.832 | |
| | Q32. I am interested in discovering any information about ADR | 0.584 | 0.689 | 0.810 | |
| | Q34. I believe that individualized medicines is the best solution to drug-related problems | 0.720 | 0.341 | 0.836 | |
| | Q35. I believe that individualized medicine can only be possible with the knowledge of pharmacogenomics | 0.569 | 0.650 | 0.814 | |
| | Q37. I think Pharmacogenetics plays essential role in reducing incidences of adverse drug reactions | 0.782 | 0.372 | 0.833 | |
| | Q38. I am comfortable reading genetic information in relation to drugs | 0.378 | 0.292 | 0.835 | |
| | Q39. I believe that Pharmacovigilance and Pharmacogenomics should be linked together for better drug safety | 0.686 | 0.354 | 0.833 | |
| | Q40. I believe legal issue retards application of genetic information into clinical practice | 0.477 | 0.304 | 0.835 | |

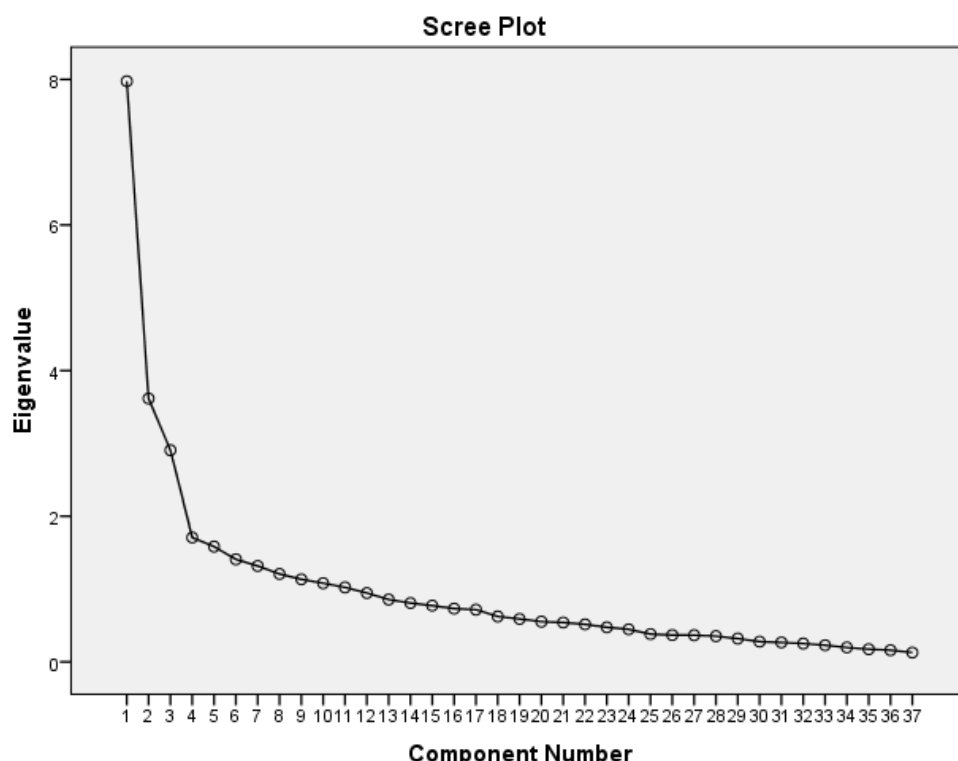
Exploratory Factor Analysis (EFA)

Exploratory factor analysis was performed by administering 49-items questionnaire to 247 subjects. From correlation matrix the $r > 0.3$ and $p\text{-value} < 0.05$ were considered as cutoff points. Kaiser-Meyer-Olkin (KMO) measure of sampling adequacy was 0.804 which is meritorious and was considered adequate for the factor analysis. The significant Bartlett's test of sphericity $p\text{-value} < 0.001$ indicates that there are worthwhile correlations among the items, therefore, fit for structure

elucidation. The communalities (extraction) values are all above 0.5 (Practically communality > 0.25), considering factor loading > 0.5 is acceptable in Communalities (extraction) for Convergent validity, thus variance = square of factor loading $0.5^2 = 0.25$. Factors were extracted using Principal Component Analysis and Varimax with Kaiser Normalization (orth.) rotation. Finally, three factors were extracted based on several considerations, i.e., Eigenvalue, Scree plot (Figure 1.) and factor loadings (Fabrigar *et al.*, 1999; Ledesma *et al.*, 2007) as shown in Table 2, 3 and 4.

Table 4: Results of Exploratory Factor Analysis (EFA)-Factor 3

| Factor | Item | Factor Loading | Corrected item Total Correlation | Cronbach's Alpha If item Deleted | Cronbach's Alpha |
|----------|--|----------------|----------------------------------|----------------------------------|------------------|
| Practice | Q41. I attempted drug related case study questions | 0.718 | 0.701 | 0.884 | 0.897 |
| | Q42. I ask information about ADRs | 0.482 | 0.492 | 0.897 | |
| | Q43. I related genetic variation to ADRs | 0.727 | 0.700 | 0.884 | |
| | Q44. I discuss about ADRs with friends etc.. | 0.514 | 0.530 | 0.895 | |
| | Q45. I attended lectures that is association with effects of genetics variations on drug therapy | 0.700 | 0.693 | 0.884 | |
| | Q46. I was trained on how to identify ADRs in pharmacovigilance during my program | 0.783 | 0.701 | 0.883 | |
| | Q47. I was trained on how to report ADRs in pharmacovigilance | 0.778 | 0.676 | 0.885 | |
| | Q48. I have had a formal training on pharmacovigilance program | 0.751 | 0.663 | 0.886 | |
| | Q49. I employed the idea of human genetic variation when trying to solve drug-related case study questions | 0.771 | 0.671 | 0.886 | |
| | Q50. I update my knowledge on genetic information in relation to drugs | 0.696 | 0.628 | 0.889 | |

**Fig. 1:** Scree Plot for factor Analysis

DISCUSSION

The questionnaire was designed to be a self-administered questionnaire, and it could also be completed through an in-person interview, computerized administration, online or by telephone after some modification and validation studies. It shows that the face validity index-clarity (FVI-Clarity) of 0.80, face validity index- comprehension (FVI-comprehension) was 0.87 and total face validity index (FVI) of 0.835 all values fall above 0.5 cutoff point, hence acceptable. The results of Content validity index (CVI) from seven experts were all greater than 0.5 and were considered acceptable and meritorious. Based on KMO >0.70 the items share common factors and it is a worthy and adequate sample. Moreover, a significant Bartlett's test of Sphericity indicates that there are worthwhile correlations among our items based on the correlation matrix. For practical purpose, we

considered >0.25 cut-off point, considering factor loading >0.5 is acceptable in Communalities (extraction) for Convergent validity, Variance is equal to square of factor loading (Hair *et al.*, 2009). Three factors were extracted based on several considerations, i.e., Eigenvalue, Scree plot & factor loading (Fabrigar *et al.*, 1999; Ledesma *et al.*, 2007). The extraction method used was "Principal Component Analysis" and Varimax with Kaiser Normalization (orthogonal) rotation to get a maximum variance explained (Hair *et al.*, 2006). In general, all the results from psychometric tests of the questionnaire showed satisfactory values. Reliability of the questionnaire as measured by the Cronbach's Alpha coefficient for each three scales and for whole at once exceeded the recommended value of 0.5.

This finding is similar to other findings with CVI and CVI far higher than 80% which were recommended minimum acceptable limit for a new tool (Boggess *et al.*, 2011; Ghasemi *et*

al., 2012; Martiniuk *et al.*, 2007; McEvoy *et al.*, 2010; Salcedo-Rocha *et al.*, 2011). We have not seen published data on the validity and reliability from similar questionnaires which we could compare our findings. Therefore, we have compared our results with standard indices like 0.7 for Cronbach's Alpha and 80% for CVI. Notwithstanding, this finding is similar to other KAP studies (Ghasemi *et al.*, 2012; Grant and Davis, 1997; Johnston *et al.*, 2003; Rosebraugh *et al.*, 2003; Sirajudeen *et al.*, 2012).

The results of factor analysis revealed a strong cluster structure, suggesting that the questionnaire meets the intended domains and could be interpreted as a one-dimensional element by the summation of all items. Table 2, 3 and 4 shows that the satisfactory values have indicated that the extracted components represent the intended domains well, and there was no need to extract another component. A factor loading cutoff of > 0.30 was adopted. Each factor explained 2.91 to 7.98% of the total variance, and 67.45% of the total variance was explained by these 11 factors, revealing a fair factor structure. Hence, the questionnaire should be interpreted as the sum of all items. According to results from factor analysis, the extracted factors confirmed that there are sufficient numbers of questions in each subdomain that explained most of the important aspects of intended to be measured by this questionnaire. This study involved both public and private Universities, different gender and location. Final-year Medicine and Pharmacy students were involved because we believe that they must have taken almost all the prerequisite courses for graduation from school to start practice under supervision. Therefore, the questionnaire for this study could reliably be used for measuring KAP concerning pharmacogenovigilance in drug safety amongst a broad spectrum of a future healthcare professional in Malaysia.

CONCLUSION

The results from this study revealed that the questionnaire assumed acceptable for cluster structures. Therefore, it should be interpreted as a one-dimensional element by the summation of all items. The questionnaire is a valid and reliable measure of final-year Medicine and Pharmacy students' KAP status concerning pharmacogenovigilance in drug safety in Malaysia.

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